

DRUG PRICING IN INDIA: REGULATIONS TO FOSTER INNOVATION, ACCESSIBILITY AND AFFORDABILITY

JULY 2018



CONTENTS

Executive Summary	4
Issue and Context	5
Healthcare Sector in India	7
Importance of the Pharmaceutical Sector	9
Pricing Regulations and their Impact	11
A. Policies and Institutions	
B. Impact on Affordability, Accessibility and Future Innovation	
Global Practices on Drug Price Regulations	13
A. International Practices for Price Controls	
B. Case of the UK	
Recommendations	15
Conclusion	17



EXECUTIVE SUMMARY

India's health sector is estimated to be worth US\$160 billion annually, and private firms play a crucial role in delivering services. The pharmaceutical and medical device segments together make up more than one-fifth of revenues. Though India has made substantial progress on some health indicators over the last few years, several challenges remain. One is the government's need to ensure drugs and medical devices are affordable to patients. Policy regulations such as National Pharmaceutical Pricing Policy, National List of Essential Medicines, and Drug Price Control Orders achieve this by capping the price of drugs and medical devices.

On-the-ground evidence and secondary research suggest drug affordability doesn't always translate to availability. Excessive price regulations often distort market competition. Because of declining revenues, drug companies may exit the market. This has a bearing on availability in the short-term. With fewer resources available, companies may also refrain from expanding to rural areas or investing in newer formulations even where there is large epidemiological evidence suggesting demand. This has a longer-term impact on the health of citizens.

Several developed as well as developing economies use a combination of methods to achieve inclusive healthcare. Incentive systems for pharmaceutical and medical device manufacturing companies play a role. The methods include having an annual prescription budget; setting a maximum reimbursement level for patients; determining the market price for patented drugs based on prices of similar drugs in other countries; and centralised drug procurement in bulk. In the UK, the legislation secures a reasonable price for branded and licensed prescription drugs for the National Health Service, at a level that allows pharmaceutical producer firms to achieve a fair return on their investment in research and development.

It is important for India to follow the lead of many established healthcare markets in striking an optimum trade-off between public need and business sense. This will make quality healthcare accessible to India's present and future generations.

ISSUE AND CONTEXT

India's National Health Policy 2017 places a strong emphasis on preventive and promotive healthcare and universal access to good quality healthcare services¹. As a means to achieve its health policy objectives, the central government is preparing to rollout a national health protection scheme which aims to provide the poorest 100 million households a sizable insurance cover². This scheme will come at a time when the country is dealing with rising cases of non-communicable diseases — such as diabetes, heart ailments and cancer — on top of its existing high burden of infectious illnesses.

PROVIDE THE POOREST
100 MILLION
HOUSEHOLDS A SIZEABLE
INSURANCE COVER

Affordable medicines and medical equipment are essential for tackling health challenges, and the private sector plays a crucial role here. Firms invest in research, and constantly strive to lower cost and expand their market. Increased revenue as a result of increased sales and a wider consumer base allows them to reinvest in developing more effective formulations, or even look for cures for currently untreatable conditions.

Governments also use legislations to keep drug and device prices at affordable levels. The Drug Price Control Order of 2013, currently being implemented by India's National

Pharmaceutical Pricing Authority, aims to achieve this very objective. The argument in favour of regulations and price controls is that while ensuring safety and efficacy, drugs must remain within the economic means of the population that needs it. They are necessary because the information asymmetry between doctors and patients does not allow the desired interaction between the demand and supply forces, resulting in the failure of consumer choice-driven price competition.

While the regulations are aimed at reducing out-of-pocket expenditures and correcting the information asymmetry, they also work in ways that distort the market. Reduced revenues often compel pharmaceutical firms and device makers to exit the space. They also impede investments and future innovation in the industry.

A study spanning 19 countries over a 13-year period³ found that regulations significantly reduced pharmaceutical revenues, with direct price controls having the biggest impact of them all. Though the legislations led to reduced costs for patients in the short-term, it had a negative impact on future innovation, often delaying the launch of new drugs.

Therefore, India needs a regulatory framework that looks beyond price caps and upfront device costs. What is required is a sound strategy

that can balance public needs and business sense, to resolve the prevailing healthcare challenges in the country.

By examining the issues above, this paper aims to facilitate a better understanding on the effectiveness of regulations and drug and device price controls, and on how these have impacted innovation, investments in R&D, healthcare access for the poor and rural communities, and patient choice. Drawing from international best practices, the paper also offers alternative views on the functioning of commercial markets, and what steps could be taken by policymakers in India to make the healthcare system more inclusive.

Sources

1. Government of India, Press Information Bureau (2017), National Health Policy 2017, [Online], Available: <http://pib.nic.in/newsite/PrintRelease.aspx?relid=159376>, Accessed May 29 2018
2. Financial Times, (May 08, 2018), "India's healthcare: does Modi have the right cure?", [Online], Available: <https://www.ft.com/content/a37648b0-4e00-11e8-8a8e-22951a2d8493>, Accessed on May 02, 2018
3. Rand Health Affairs, (2009), "The Effect of Regulation on Pharmaceutical Revenues: Experience In Nineteen Countries".

HEALTHCARE SECTOR IN INDIA

The Indian healthcare sector is estimated to be a US\$ 160 billion industry, growing at a compounded annual rate of roughly 15 per cent⁴. Pharmaceuticals, and medical equipment and supplies constitute 22 per cent of the sector's total revenues.

INDIAN HEALTHCARE SECTOR
IS ESTIMATED TO BE A

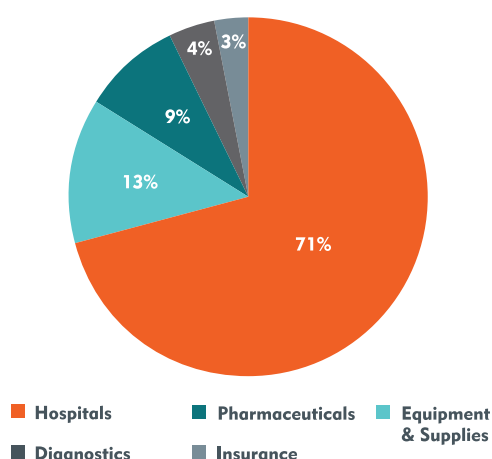
\$ **160**

INDUSTRY

GROWING AT A COMPOUNDED
ANNUAL RATE OF

15%

HEALTH SECTOR REVENUE
SPLIT IN PERCENTAGES

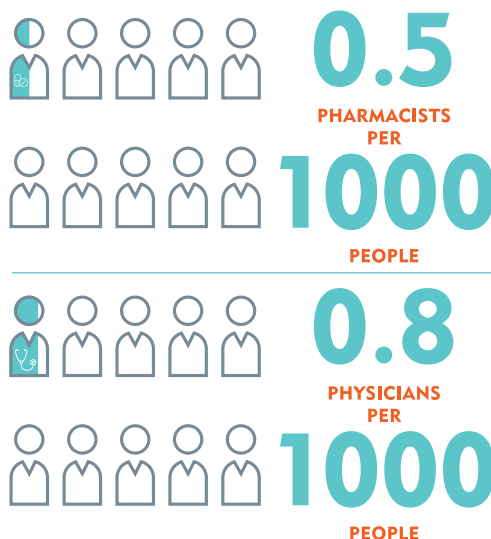


Although the health of the Indian population has shown signs of improvement over the past few decades, it still falls short on many key indicators. For example, though life expectancy and nutrition levels

have risen considerably, the disease burden continues to remain high. Non-communicable diseases alone account for nearly 61 per cent of all deaths in India⁵.

Similarly, India's healthcare expenditure (government plus private) as per centage of GDP is lower than those of comparable economies⁶. Data from the Economic Survey 2017-18 suggest the public healthcare expenditure, of the central and state governments combined, as per centage of GDP has remained between 1.1 and 1.5 per cent per year over the last five years⁷.

The system is also strained by rising costs and a shortage of physicians, nurses and other human resources⁸. There are roughly 0.5 pharmacists per 1,000 people in the country⁹. The number of physicians is 0.8 per 1,000 people – roughly less than half of the world average¹⁰.



Sources

4. India Brand Equity Foundation (2018), "Sector Report: Health", [Online], Available: <https://www.ibef.org/industry/healthcare-presentation>, Accessed May 02, 2018

5. Times of India, (September 20, 2017), "Non-communicable diseases cause 61% of deaths in India: WHO report", [Online], Available: <https://timesofindia.indiatimes.com/life-style/health-fitness/health-news/non-communicable-diseases-cause-61-of-deaths-in-india-who-report/articleshow/60761288.cms>, Accessed May 02, 2018

6. World Bank, (2015), "Current Health Expenditure", [Online], Available: <https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?end=2015&locations=IN-ID-BR-ZA-CN-SG-NP-LK&start=2015&view=bar>, Accessed on April 10, 2018

7. Economic Survey 2017-18 (2018), Retrieved from http://mofapp.nic.in:8080/economicsurvey/pdf/167-185_Chapter_10_Economic_Survey_2017-18.pdf

Sources

8. Financial Express, (June 29, 2017), "Delivering healthcare in India: How to overcome barriers to innovation", [Online], Available: <https://www.financialexpress.com/opinion/delivering-healthcare-in-india-how-to-overcome-barriers-to-innovation/740320/>, Accessed May 02, 2018

9. World Health Organisation (2011). Global Health Observatory Data Repository. Available: <http://apps.who.int/gho/data/node.main.A1444>

10. The World Bank (2016), Physicians per 1,000 population, [Online], Available: <https://data.worldbank.org/indicator/SH.MED.PHYS.ZS>, Accessed May 02, 2018

11. Netherlands Enterprise Agency (2014), Healthcare Market in India [online], Available: <https://www.rvo.nl/sites/default/files/2017/08/Healthcare-Market-in-India.pdf>

12. World Bank (2001), "The Poor and Health Service Use in India" [Online], Available: <http://siteresources.worldbank.org/healthnutritionandpopulation/Resources/281627-1095698140167/Mahal-ThePoorAnd-whole.pdf>

13. Deloitte (2016), Global Healthcare Outlook [Online], Available: <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2016-health-care-outlook.pdf>

The private sector has a strong presence in India — roughly 80 per cent of all healthcare delivery takes place through private healthcare providers¹¹.

80%

OF ALL HEALTHCARE DELIVERY TAKES PLACE THROUGH PRIVATE HEALTHCARE PROVIDERS

The World Bank, in a national study in India in 2001, estimated that 82 per cent of all doctor visits are to private providers¹².

WORLD BANK STUDY IN INDIA 2001 ESTIMATES



82%

OF ALL DOCTOR VISITS ARE TO PRIVATE PROVIDERS

Private hospitals in the country are growing at an annual rate of 12 per cent. Private entities have contributed 70 per cent of the hospital beds added over the past decade¹³.

PRIVATE HOSPITALS IN INDIA ARE GROWING AT AN ANNUAL RATE OF

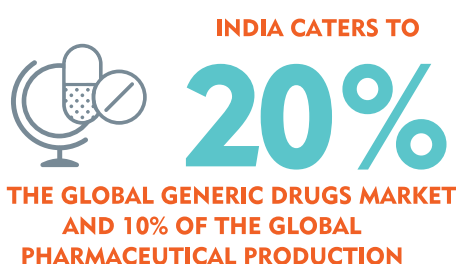


12%

Out-of-pocket medical expenses continue to remain high in India. They make up about 68 per cent of all healthcare costs in the country, as against a world average of 18 per cent. This is because the Indian insurance sector is still in its infancy. Data from The Insurance Regulatory and Development Authority of India suggest that, currently, health insurance makes up just one-fourth of the non-life insurance market. This per centage will, however, go up significantly after the central government rolls out new health insurance programmes.

IMPORTANCE OF THE PHARMACEUTICAL SECTOR

India accounts for roughly 20 per cent of the global generic drugs market, and for 10 per cent of the global pharmaceutical production. Low cost of production, research and innovation and the availability of skilled labour are the key drivers.



The India Brand Equity Foundation estimates that in 2016-17, the pharmaceuticals industry revenue was roughly US\$ 27.57 billion.



That year, the medical technology industry had a revenue of roughly US\$ 7.8 billion.

Together, they constitute roughly 22 per cent of the healthcare industry revenue. Both these segments are expected to grow strongly, at a rate between 10 and 15 per cent per year.

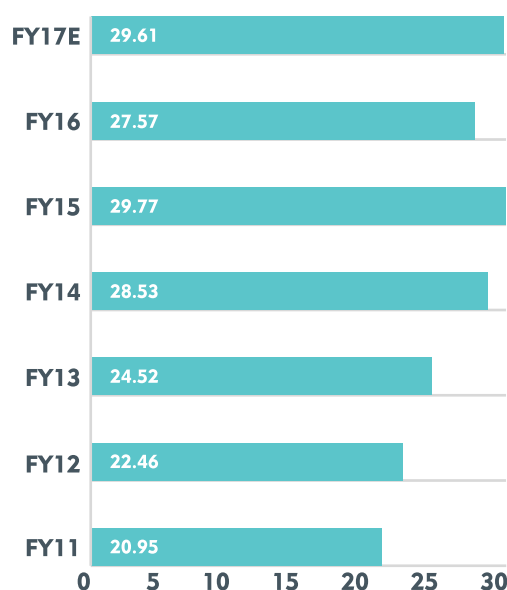
Indian regulations allow up to 100 per cent FDI for Greenfield projects under automatic route, and 74 per cent for pharmaceutical projects. According to the Department of Industrial Policy

and Promotion, the pharmaceuticals sector attracted a cumulative FDI worth US\$ 15.71 billion between April 2000 and March 2018¹⁴.

The Indian pharmaceutical market is estimated to be close to roughly US\$ 30 billion in 2017-18. After a high growth from 2010-11 to 2015-16, the revenue dipped considerably in 2016-17. It is expected to attain its 2015-16 level again in 2017-18.



REVENUE OF INDIAN PHARMACEUTICAL SECTOR (BILLION US\$)



Sources

14. DIPP, (2018), "Fact Sheet on Foreign Direct Investment" [Online]. Available: http://dipp.nic.in/sites/default/files/FDI_FactSheet_29June2018.pdf, Accessed on July 08 2018

15. IBEF (June 2018), "Indian Pharmaceutical Industry", [Online], Available: <https://www.ibef.org/industry/pharmaceutical-india.aspx>, Accessed on July 9, 2018

Source: India Brand Equity Foundation June 2018 report¹⁵

As in other economies, the pharmaceutical industry in India is characterised by high R&D failure rates. Companies suffer repeated losses on their investments in a process that is long and risky. Transition rates of drug candidates through clinical trials also are poor¹⁶.

In India, the overall success rate of new drug development is low, and the timelines are long. It takes an average of over 10 years to go from preclinical to confirmatory stage, as illustrated in the table below.

ATTRITION RATES AND TIMELINES OF DRUG DEVELOPMENT IN INDIA

CLINICAL DEVELOPMENT STAGES	SUCCESS RATE (%)	TIMELINES (YEARS)
PRECLINICAL	50.3	1.9
PHASE 1 - HUMAN PHARMACOLOGY	54.0	2.5
PHASE 2 - THERAPEUTIC EXPLORATORY	17.4	3.4
PHASE 3 - THERAPEUTIC CONFIRMATORY	33.3	3.0

Source: The Drug Discovery and Development Industry in India—Two Decades of Proprietary Small-Molecule R&D¹⁷

Sources

16. MPRA, (2018), "National Drug Policy Face-off: Some Notes Justifying the Regulations and Drug Price Control Regime in India", [Online], Available: https://mpr.ub.uni-muenchen.de/84318/1/MPRA_paper_84318.pdf, Accessed on April 20, 2018

17. Differding, E. (2017). The Drug Discovery and Development Industry in India—Two Decades of Proprietary Small-Molecule R&D. *Chemmedchem*, 12(11), 786–818. <http://doi.org/10.1002/cmdc.201700043>

PRICING REGULATIONS AND THEIR IMPACT

A. Policies and Institutions

Drug prices in India are directly controlled by the Drug Price Control Order (DPCO), issued by the government under the Essential Commodities Act, 1955. This act authorises the government to fix prices of essential bulk drugs and their formulations. India had no regulations in place for drug prices until 1962. The regulations existing at that time were meant to manage drug import, export, manufacture and distribution. Since then, the DPCO has been amended half a dozen times, and now covers a bulk of formulations, scheduled drugs and non-scheduled drugs.

In the 1970s, the government also introduced the Patents Act, which recognised 'process patents'. It was not a direct price control mechanism, but had a massive impact on reducing drug prices in India, enabling the country to become a global player in the generic drugs market. The act was amended in 2005, to reintroduce 'product patents', and this did increase R&D spending. The number of patents granted, however, has not gone up in the last decade¹⁸.

In 1997, the Indian government established the National Pharmaceutical Pricing Authority (NPPA) to regulate the prices of scheduled and non-scheduled drugs. In 2013, the NPPA was authorised to regulate the prices and availability of all drugs mentioned in the National List of Essential Medicines (NLEM),

causing a huge drop in the prices of the 348 essential drugs originally included in 1979.

Following changes made to the NLEM in 2016, coronary stents are now considered as essential drugs. In 2017, the NPPA capped the price of various models of stents and knee implants, bringing its prices down by around 50 per cent.

Recent media reports suggest that DPCO of 2013 may be further amended to cap trade margins charged by drug stockists and chemists. The NLEM list may also be expanded again.

B. Impact on Affordability, Accessibility and Future Innovation

Reduced prices make the drugs affordable, but often at the cost of availability. A 2015 study by IMS Health suggests that regulations that push for price levels below market value cause suppliers to withdraw from the market, negatively impacting those in need of these medicines. For example, there was a serious shortage of furosemide or furosemide, a lifesaving paediatric drug prescribed for heart ailments, after the NPPA reduced its price by about 90 per cent in November last year. The regulator had to revise the price cap in June this year¹⁹.

Similarly, an IIM Ahmedabad research paper on the impact of price controls on drug sales volume strongly suggests that there was a significant

Sources

18. MPRA, (2018), "National Drug Policy Face-off: Some Notes Justifying the Regulations and Drug Price Control Regime in India", [Online], Available: https://mpr.ub.uni-muenchen.de/84318/1/MPRA_paper_84318.pdf, Accessed on April 20, 2018

19. Indian Express, (June 29, 2018), "Drop in supplies: Price of key drug for kids with heart ailment hiked", [Online], Available: <https://indianexpress.com/article/lifestyle/health/drop-in-supplies-price-of-key-drug-for-kids-with-heart-ailment-hiked-5237978/>, Accessed on June 30, 2018

decrease in sales volume post-price control, indicating decreased access for patients²⁰.

Unsustainability due to thin margins also acts as an entry barrier for new firms wanting to set foot in the market. The existing firms, because of their reduced revenues, lack sufficient resources to expand into the rural markets, where drug availability is required the most.

technology medical devices to the same price control measures as older technology products. This results in technologically-advanced devices to be sold at a greater loss, compared to products based on older technologies — further limiting R&D investments.

There is also little evidence to support the idea that reducing the price of a device proportionately reduces the cost of the medical procedure. An IQVIA-ADVAMED survey suggests relatively limited benefits to patients. There has been no significant growth in procedure volumes in hospitals. Even government hospitals surveyed for the study recorded no notable increase in the number of angioplasty procedures performed²¹. This could also be because, as some media reports anecdotally suggest, hospitals have increased service charges to offset the loss of margins on stents and knee implants.

Arbitrary price controls also have a depleting effect overall on future innovation. A report by IMS Health reveals that price control measures have caused a 75 per cent decline in new drug launches since 2011²². A limitation of the current regulations is that they do not distinguish between advanced technologies within the same medical device or product class. It subjects newer

Sources

20. IIM-A, "Does Pharmaceutical Price Regulation Result in Greater Access to Essential Medicines? Study of the impact of drug price control order on sales volume of drugs in India", [Online], Available: <https://web.iima.ac.in/assets/snippets/workingpaperpdf/2217512512016-02-01.pdf>, Accessed on May 10, 2018

21. Advamed, (2018), Medical devices in India - an agenda to effective healthcare delivery, [Online], Available: https://www.advamed.org/sites/default/files/resource/medical_devices_in_india_-_an_agenda_to_effective_healthcare_delivery.pdf, Accessed on April 20, 2018

22. IMS Health (2018), "Assessing the Impact of Price Control Measures on Access to Medicines in India"

GLOBAL PRACTICES ON DRUG PRICE REGULATIONS

A. International Practices for Price Controls

The WHO guideline on country pharmaceutical pricing policies suggests countries should use a combination of different pricing policies based on their regional needs²³. Meanwhile, the UN favours a balance between the conflicting demands of trade and the right to health. In its September 2016 report, the UN High-Level Panel on Access to Medicines backed 'de-linkage' of the costs of R&D from the eventual price of the drug through some agreements funded by governments or philanthropists that reward companies for getting a much-needed drug, like an antibiotic, into the hands of doctors²⁴. It also recommends that governments should build on existing systems, such as the Global Price Reporting Mechanism and Vaccine Product, Price and Procurement, to establish and maintain an international database of prices of patented drugs, biosimilars and generics in the public and private sectors of all countries where they are registered.

A 2009 Rand Corporation study found that, between 1992 and 2004, a range of pricing regulations existed across countries that were aimed at making drugs more affordable to patients. A few of its observations were:

- in Germany, policies allowed for an annual budget for physicians for prescriptions, with financial sanctions in the event of overruns;
- countries like Spain and Turkey

imposed a maximum annual limit on profits and profit growth rates of pharmaceutical companies;

- the drug pricing regulators in the Netherlands and Italy had set a maximum reimbursement level or market price for patented drugs based on prices of similar drugs in other countries;
- a few regulators, especially in Europe, set prices of patented drugs using price negotiations, often based on patented drug price in similar markets across the globe;
- a few countries used generic and therapeutic reference pricing systems where the regulator sets a reference price, i.e., a level above which consumers will not be reimbursed for the cost of a drug; and
- in New Zealand, an economic evaluation had to be considered when deciding on the inclusion of a drug in the benefit package offered by the National Health Insurance, government or private insurers, or when determining the level of reimbursement.

There are regulatory frameworks that support innovation in other countries, too. For example, Japan has historically rewarded innovative drugs with high reimbursement prices, strong patent protection, unrestricted access to doctors, exemptions from price revisions during the patent life, and timely regulatory review²⁵. Since 2002, the country has also encouraged substitution of branded drugs with generics.

Sources

23. WHO, (2015), "WHO Guideline on Country Pharmaceutical Pricing Policies"

24. UN, (2016), United Nation Secretary General's High Level Panel on Access to Medicines, [Online], Available: <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>, Accessed May 02, 2018

25. EFPIA and PhRMA, (2017), "Consequences Expected from the Final Drug Pricing Reform Package", [Online], Available: http://efpia.jp/link/171220_PhRMA_EFPIA_Joint_Press_Statement_Consequences_Expected_from_Final_Drug_Pricing_Reform_Package_E.pdf, Accessed on 29 June, 2018

Mexico is another good example. It is a developing country with an increasing challenge of making healthcare more inclusive. The country's centralised drug price negotiation process takes advantage of the combined bargaining power of various public sector entities to achieve lower prices for patented single-source drugs²⁶. This mechanism has generated significant savings, as well as other positive externalities, such as increased certainty for purchasers and suppliers about price, more efficient purchasing processes and a greater understanding of the market for the government.

B. Case of the UK

The prices of branded prescription drugs have been regulated in the UK since 1957, in accordance with a voluntary agreement called Pharmaceutical Price Regulation Scheme, (PPRS) between the Association of the British Pharmaceutical Industry and the UK Department of Health.

This agreement applies to all branded, licensed prescription drugs available on the National Health Service (NHS)²⁷. It aims to secure reasonable prices for the NHS while ensuring that a pharmaceutical producer can achieve a fair return on its investment in R&D. When a company that supplies branded drugs to the NHS does not sign up for the voluntary PPRS, the prices it charges to the NHS are regulated by

a different legislation, called Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008.

The PPRS does not apply to generic version of a drug once it has been de-branded. In the past, this allowed some companies to buy de-branded drugs not available from other companies, and then significantly increase its prices²⁸.

Last year, the UK enacted the Health Service Medical Supplies (Costs) Act to regulate this practice. The main purpose of the act was to prevent pharmaceutical companies from hiking the prices of generic medicines over which they have a virtual monopoly. In addition, the act clarifies the government's authority to request companies to make payments to control the cost of medicines. Organisations are liable for financial penalties should they fail to comply with regulations created under the new law, which may include exceeding a price cap or failing to record or provide requested information under a statutory scheme. The regulation also strengthens the basis on which the government can collect data on the sale and purchase of medicines from all parts of the supply chain. The key purpose of obtaining this data is to assess the sums reimbursed to pharmacists for medicines. This enables the government to calculate reimbursement figures which will more accurately reflect market prices.

Sources

26. Inter-American Development Bank, (2016), "Breve: Mexico's Coordinating Commission for Negotiating the Price of Medicines and Other Health Inputs".

27. Hausfeld, (2017), "Is the Current UK System of Pharmaceutical Price Regulation Working?", [Online], Available: <http://www.hausfeld.com/news-press/is-the-current-uk-system-of-pharmaceutical-price-regulation-working>, Accessed on 20 April, 2018

28. The Pharmaceutical Journal, (2017), "The Medical Costs Act – What it means for Pharma", [Online], Available: <https://doi.org/10.1211/pj.2017.20203330>, Accessed on 20 April, 2018

RECOMMENDATIONS

The Three Year Action Agenda (2017-18 to 2019-20) of Indian government think tank NITI Aayog²⁹ made an important observation: “A balanced approach towards regulation is needed for achieving the twin objectives of access to medicines and a strong pharmaceutical industry. There is a trade-off between lower prices on the one hand and quality medicine and discovery of breakthrough drugs on the other. It is therefore recommended that Drug Price Control Orders may be delinked from the National List of Essential Medicines.” This suggests policy experts are aware of the limitations under which private healthcare players, including pharmaceutical firms, have to operate.

Pharmaceutical companies are themselves exploring different financing models that might ease the cost burden of drugs and medical devices on patients. That said, in the context of a developing country like India, some policy recommendations for assuring affordability of drugs without impacting future innovations could be the following:

1. The regulator should set prices of patented drugs using price negotiations. This could be based on the market price of similar patented drugs in other countries — a common practice in many nations. For example, since 1996, prescription drug prices in the Netherlands are based on wholesaler prices in Belgium, France, Germany and the UK.
2. Reference Pricing could be adopted. The regulator should sets a reference price, i.e., a level above which consumers will not be reimbursed for the cost of a drug. In several countries, bundled pricing or the Diagnostic Related Grouping (DRG) system has become a norm. This system proposes a fixed payment amount that an insurance company pays to hospitals for a procedure. This system divides possible diagnoses into more than 20 major body systems, and subdivides them into almost 500 groups for the purpose of reimbursement. If hospitals spend lower than the DRG, they make money, and, if costs go up, they lose.
3. Economic evaluation must be considered when deciding on the inclusion of a drug in the benefit package offered by the National Health Insurance, government or private insurers, or when determining the level of reimbursement. For example, New Zealand has used cost-utility analysis (based on measuring cost per quality adjusted life-year) as a key analytical tool in its management of drug subsidies.
4. Negotiation and bulk procurements could be critical alternatives to the price control mechanism for maintaining affordability of drugs. Large-scale procurement by the government will help keep medicine prices low,

Sources

29. Niti Aayog, The Three Year Action Agenda 2017-18 to 2019-20, [Online] Available: http://niti.gov.in/writereaddata/files/coop/India_ActionAgenda.pdf, Accessed on 24 June 2018

especially in government facilities. Procurement strategies need to be rational and stable. Very often, procurement at the state level is complicated and vague. Payments are not made for years, and this makes large-scale negotiations with governments difficult and ineffective.

5. Policymakers may also consider de-linking the costs of R&D from the eventual price of the drug. This can be achieved through some sort of deal funded by the government that rewards companies for making a new drug or formulation available in the market.
6. Innovation must be encouraged to tackle neglected diseases. The pharmaceutical sector should be incentivised to explore neglected diseases and their treatment. This would bring down prevalence of diseases that cause a huge burden on the economy.
7. It is also important to look at the difference between in-patient costs and the costs of treating out-patients. It is often hospitalisation costs that cause hospital bills to bulge, and these must be looked at when calculating price caps.
8. Increased health literacy and generation of awareness on self-care can help significantly in the prevention of non-communicable chronic diseases, such as cardiovascular diseases, cancer and diabetes. OTC (Over-the-Counter) medicines play an important role in self-care, and are hence not subjected to price controls in most countries. The Indian government is also urged to remove price controls on the OTC market, and allow manufacturers to set their own prices for non-prescription medicines that are not reimbursed based on market conditions. This will encourage more players to enter the market and invest, ensuring availability of OTC medicines and adequate price competition, as well as future innovation³⁰.
9. The issue of healthcare access must be tackled through genuine Public Private Partnerships, helping the health sector leverage the strengths of both the large state sector and the cutting edge technology that the private sector brings.
10. Last but not the least, countries should collaborate and promote exchange of information about policies and their impacts on pharmaceutical prices.

Sources

30. Reckitt Benckiser, "OTC Medicines: Self Care in India"

CONCLUSION

Increasing out-of-pocket expenditure of patients, a large share of which is on purchase of drugs, is a matter of growing concern for the government in India. Regulations such as Drug Price Control Orders and National List of Essential Medicines attempt to control prices of drugs and medical devices. They are intended to reduce the cost burden on patients, and therefore to make quality healthcare available to millions of families.

While pricing regulations make drugs affordable in the short-term, they may not let drugs remain accessible to patients in due course. Accessibility depends on availability, and pharmaceutical companies play a crucial role in making drugs available in the market. Excessive price control reduces firms' revenues, prompting them to limit production, or even cease their operations. Firms may also not remain willing to expand to rural markets.

Regulations and price control also have a direct impact on R&D investments in drug development, and may therefore have a detrimental effect on future public health. Finding cures for untreated diseases or coming up with better and more-effective drug formulations takes sizable investment in terms of time and resources.

Pharmaceutical regulation therefore involves a potential trade-off between curbing costs today and having fewer drugs to effectively continue treating diseases tomorrow. Therefore, India needs to strike a balance, as mature healthcare markets in many countries have, so that its citizens have access to quality healthcare now and in the future. It may look at good practices in advanced and developing countries to design as well as implement policies that can strike such a balance.

Author

Dr Amir Ullah Khan - Director Research at Aequitas and Adjunct Professor of Health Economics at Manipal Institute of Technology

UK INDIA

BUSINESS COUNCIL

WHO ARE WE?

The UK India Business Council believes passionately that the UK-India business partnership creates jobs and growth in both countries. Through our insights, networks, and policy advocacy, we support businesses to succeed.

GET IN TOUCH

UK INDIA BUSINESS COUNCIL LONDON

12th Floor, Millbank Tower
21-24 Millbank London SW1P 4QP
enquiries@ukibc.com
Tel: +44 (0)20 7592 3040
+44 (0)800 0196 176

UK INDIA BUSINESS CENTRE MUMBAI

Trade Centre G/F & 1st Floor,
Bandra East,
Mumbai,
Maharashtra 400051
enquiriesindia@ukibc.com

UK INDIA BUSINESS CENTRE BANGALORE

Concorde Towers, UB City,
1 Vittal Mallya Road, Level 14 & 15,
Bengaluru, Karnataka 560001
enquiriesindia@ukibc.com
Tel: +91 (0) 806 7590 319

UK INDIA BUSINESS CENTRE GURGAON

16th Floor, Tower 9A, Cyber City,
DLF City Phase II,
Gurgaon Haryana – 122002
enquiriesindia@ukibc.com
Tel: +91 (0) 124 4155 700

DOING BUSINESS IN INDIA HELPLINE

For support call 0800 0196 176

WEBSITE

www.ukibc.com